

REMARKS

This preliminary amendment is filed with a Request for Continued Examination for the above-identified patent application. The applicants very much appreciate the time the Examiner extended to the undersigned representative in an interview on August 15, 2002. In that interview, the Examiner suggested that the applicants substitute the pending claims with a new set of claims directed to granule compositions and remove multiple claim dependencies. The Examiner also suggested that the independent claim include a size limitation for the particles so that the claimed granules are clearly distinguished from the compositions discussed in the Parker *et al.* document. Independent claim 68 as well as its dependent claims 69-95 also characterize the microorganisms as being dead and non-disrupted, and characterize the granules as being porous. The applicants respectfully submit that the various limitations set forth in claim 68 descriptively characterize granule compositions described in the specification and distinguish these inventive compositions from compositions discussed in documents cited in the final Office action.

Support for the descriptive limitations of the new claims are found throughout the specification. For example, the specification describes extruded microorganisms of claims 68 and 86 (*e.g.* page 15, lines 11-21), non-disruptive organisms of claim 68 (*e.g.* page 5, lines 6-7 and page 6, lines 10-17), porous microorganisms of claims 68 and 91-93 (*e.g.* page 20, lines 11-12), microorganisms having a specified diameter of claims 68 and 87-90 (*e.g.* page 19, lines 15-26), specific microorganisms of claims 69-75 (*e.g.* page 7, lines 11-26), specific components in the microorganisms of claims 76-82 (*e.g.* page 8, lines 8-26), specific dry matter content of claims 83-85 (*e.g.* page 5, line 35; page 5, lines 25-31; and page 12, line 22), granule structures allowing solvent access of claim 94 (*e.g.* page 6, lines 25-26), and free flowing

granules of claim 95 (*e.g.* page 19, lines 27-28). Thus, the new claims are fully supported and enabled by the specification and thereby add no new matter. As the new claims clarify issues for appeal and are commensurate with the format suggested by the Examiner in the interview, entry and allowance of the new claims is respectfully requested.

In the final Office action mailed April 29, 2002, claims 41-53 and 60-61 were rejected under 35 U.S.C. § 112, second paragraph, as the use of the symbol “Ω” allegedly was indefinite. New claims 78 and 79 make reference to “ω” polyunsaturated fatty acids in accordance with the description in the specification, and accordingly, the rejection is inapplicable to the new claims.

Claims 27-29, 41, 46 and 54 were rejected under 35 U.S.C. § 102(b), and in the alternative, under 35 U.S.C. § 103(a) in view of Parker *et al.* As discussed in the interview with the Examiner on August 15, 2002, Parker fails to disclose, teach, or suggest granules having a diameter between 0.1 millimeters to 12 millimeters as specified by claim 68. Instead, Parker describes microorganism compositions having diameters between 5 to 20 μm in diameter, which are far smaller than those claimed. Parker also fails to describe microorganism compositions produced by granulation and thereby fails to disclose, teach, or suggest a granule composition that is porous. Because the microbial compositions of Parker lack pores, these compositions cannot be utilized in the solvent extraction processes described in the present application. Thus, the microbial compositions discussed in Parker are far different than those claimed herein as they are manufactured for an entirely different utility. Accordingly, it is respectfully submitted that the rejection under Parker is inapplicable to the new claims.

The previously pending claims also were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Carduck *et al.* in combination with Parker *et al.* and Dsiezak and further

in combination with Akimoto *et al.* and Casey *et al.* This rejection is moot with respect to the new claims. Independent claim 68 is directed to granule compositions comprising extruded microorganisms that are dead and have a diameter between 0.1 millimeters to 12 millimeters. The cited documents, alone or in combination, fail to teach or suggest granules having a diameter between 0.1 millimeters to 12 millimeters. Thus, claim 68 and its dependent claims are not *prima facie* obvious because the cited combination fails to result in the claimed granule compositions.

There also was no motivation to combine the cited documents at the time the application was filed because (1) modifying the microbial compositions of Carduck would render those microorganisms inoperable for their intended purpose; (2) the utilities of the microbial compositions discussed in the cited documents are entirely different from one another, and (3) the requirements for combining the cited documents as set forth in *In re Rouffet* are not met.

The Modifications Proposed by the Office Would Render the Carduck Compositions Inoperable

Carduck discusses porous granules of active yeast that can be rehydrated. The yeast is described as having good vitality, which means the yeast are alive not dead (*see* column 1, lines 39-40). The granules are intended to be used in bakery applications, which require that the yeast are alive and can regenerate with the addition of warm water (*see* column 5, lines 11-12). This document has nothing to do with a method of extracting compounds from cells using a solvent.

The Office cites Dsiezak and Parker for the proposition that the skilled artisan would have been motivated to kill the cells of Carduck to generate a food supplement. Dsiezak is a general review document dealing with yeast and it describes active compositions and inactive dry yeast that have been pasteurized. While the document discusses the use of inactive yeast as

nutritional and flavor components, the active yeasts are of no use in the bakery applications described in Carduck since the pasteurized yeast are dead and cannot leaven bread.

Because pasteurizing and killing the yeast described in Carduck would kill them and render them inoperative for their intended purpose of leavening bread, there was no motivation to kill the yeast described in Carduck. This lack of motivation is described in *In re Fritch*, 23 USPQ.2d 1780, 1783 (Fed. Cir. 1982) and *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984), which are attached herewith as Exhibit A and Exhibit B, respectively. In *In re Fritch* the Court noted in footnote 12 that “this Court has previously found a proposed modification inappropriate for a obviousness inquiry when the modification rendered the prior art reference inoperable for its intended purposes (emphasis added).” *In re Fritch*, 1783. The Court then cited *In re Gordon* as it earlier stated that “the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification (emphasis added).” In the fact pattern set forth in *In re Gordon*, the Court held that the apparatus if turned upside down, which was the suggested modification, would be rendered inoperable for its intended purpose. *In re Gordon* at 1127.

The modification suggested here by the Office, which is to kill the live yeast manufactured by the process described in Carduck for leavening bread, would render the yeast inoperable for the intended purpose of leavening bread. As described in *In re Gordon*, there also was no motivation to kill the yeast described in Carduck because this modification would be undesirable since the yeast would no longer function for their stated purpose. Accordingly, there was no motivation to modify the live yeast in Carduck at the time the present application was filed.

The Claimed Methods and Cited Documents Share No Common Utility

As noted above, the claimed granule compositions are dead and are useful for obtaining chemical compounds via solvent extraction processes. The yeast compositions described in Carduck are alive and are stated to be useful in bakery applications, such as leavening bread, and the microorganism compositions described in Dsiezak and Parker are dead and are stated to be useful as food supplements. Thus, the stated utilities for the claimed compositions are completely different than the intended utilities for the compositions described in Carduck, Dsiezak, and Parker. In *In re Lalu*, 223 USPQ 1257, 1259 (Fed. Cir. 1984), which is attached herewith as Exhibit C, the Federal Circuit stated that an element in determining obviousness of a new composition is a motivation of one having ordinary skill in the art to make it, and noted that the “motivation is not abstract, but practical, and is always related to the properties or uses” one skilled in the art would expect the composition to have if made.

Here, the properties of the microorganisms in the claimed granule compositions are distinct from those described in Carduck because the microorganisms in the claimed granules are dead and those in Carduck are alive. Similarly, the compositions discussed in Dsiezak and Parker have different properties than those in Carduck because they too are dead. Furthermore, the stated utilities for the microbial compositions in the present application and in the cited documents are different from one another. Accordingly, there was no motivation to modify the live yeast of Carduck as established in the *In re Lalu* decision.

The Required Motivation Set Forth in *In re Rouffet* is Not Present

A copy of *In re Rouffet*, 47 USPQ.2d 1453 (Fed. Cir. 1998) is attached herewith as Exhibit D. In that decision, the Court of Appeals for the Federal Circuit reversed a finding of unpatentability made by the Board of Appeals on the basis that there was no motivation to

combine the documents cited for the rejection of Rouffet's claims. Attention is called to page 1458 of the decision where the Court identified three possible bases for motivation to combine documents.

The first listed basis, "the nature of the problem to be solved," is not found here as the claims address granulated microbial compositions that are porous and are useful for solvent extraction processes. Combining the cited documents does not advance the solution to this problem as the combination does not address microbial compositions useful for solvent extraction. Rather, Carduck discusses yeast compositions that are alive and useful for baking applications, and Parker and Dsiezak discusses dead microorganism compositions useful as food supplements.

The second basis, "the teachings of the prior art," is not found here either as there is no motivation provided by the documents themselves. Carduck focuses on maintaining the biological activity of the yeast through the manufacturing process such that the yeast compositions are alive at the end of the process. In contrast, the microbial compositions discussed in Dsiezak and Parker are focused on pasteurizing and killing the microorganisms so that they pose no threats to humans for consumption as food additives, thus, there is nothing in common with Carduck, Dsiezak and Parker that suggest a combination of these documents.

The third basis is "the knowledge of persons with ordinary skill in the art." In order to apply this basis, the Court stated that it would be necessary to "explain what specific understanding or technological principal within the knowledge of one of ordinary skill in the art would have suggested the combination" and concluded that "the Board merely invoked the high level of skill in the field of the art. If such a wrote indication would suffice to supply a

motivation to combine, the more sophisticated scientific discovery would rarely, if ever, experience a patentable technical advance.”

Here, the Office makes unsupported statements that a skilled artisan would have been motivated to modify the live yeast of Carduck by killing them. There is nothing in Carduck that teaches or suggest that the yeast should be killed. Such a modification was counter-intuitive because the yeast would then be inoperative for the stated purpose of using them in bakery applications.

Also, the CAFC commented that the knowledge of persons of ordinary skill in the art may include certain references of special importance (*i.e.*, that one or both of the cited documents is so well know that anyone in the art would be familiar with the documents). An example would be the famous Kholer and Millstein paper on monoclonal antibody preparations. Clearly, none of the cited documents here rise to this level.

Thus, it should be apparent that combining the cited documents does not comply with the standard set forth in *In re Rouffet*. As there was no motivation to combine the cited documents and because the cited documents in combination do not result in the claimed subject matter, the Office has not established a *prima facie* for obviousness. Accordingly, it is respectfully submitted that the rejection is moot in view of the new claims.

Conclusions

New claims directed to granule compositions are submitted that remove multiple claim dependencies and are commensurate with the format suggested by the Examiner in an interview on August 15, 2002. The claims are fully supported by the specification and previous rejections

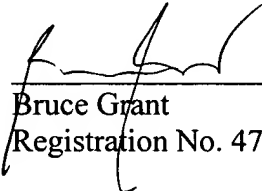
for alleged indefiniteness, anticipation, and obviousness are inapplicable. Accordingly, notice of allowance is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing Docket No. 251502006900.

Respectfully submitted,

Dated: March 25, 2003

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